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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,273	03/31/2004	Akira Ito	F-8198	7488
28107	7590	11/01/2005	EXAMINER	
JORDAN AND HAMBURG LLP 122 EAST 42ND STREET SUITE 4000 NEW YORK, NY 10168			GODDARD, LAURA B	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/815,273

Applicant(s)

ITO ET AL.

Examiner

Laura B. Goddard, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,7,10,13,16,21,22,25,28 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 5, 6, 8, 9, 11, 12, 14, 15, 17, 18, 19, 20, 23, 24, 26, 27, 29, 30, 32 is/are rejected.
- 7) ☒ Claim(s) 4,6,15,17,18,24,26-30 and 32 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. <u>10/19/05</u>                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The Election filed August 31, 2005 in response to the Office Action of July 27, 2005 is acknowledged and has been entered. Applicant's telephone election of Group III (claims 1, 4, 5, 6, 8, 9, 11, 12, 14, 15, 17, 18, 19, 20, 23, 24, 26, 27, 29, 30, 32) as drawn to a hyperthermia agent and a method for using a cytokine and hyperthermia for treatment of a malignant tumor, is acknowledged. Applicant is required to confirm this election in response to this Office Action.

Claims 1-32 are pending. Claims 2, 3, 7, 10, 13, 16, 21, 22, 25, 28, and 31 have been withdrawn from further consideration by the examiner under 35 CFR 1.142(b) as being drawn to non-elected inventions. Claims 1, 4, 5, 6, 8, 9, 11, 12, 14, 15, 17, 18, 19, 20, 23, 24, 26, 27, 29, 30, and 32 are currently under prosecution.

### ***Claim Objections***

2. Claims 4, 6, 15, 17, 18, 24, 26-30, and 32 are objected to for containing subject material that is drawn to a non-elected invention or being dependent on a claim of a non-elected Group. The claims recite "according to Claim 1 or 2" (claims 4, 6, and 15) or "a vector in which a cytokine gene is integrated so that cytokine can express in malignant tumor cells" (claims 15, 17, 18, 24, 26, 27, 29, 30, and 32). Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 20 recites "A hyperthermia method of malignant tumor" wherein a verb is missing or the action of the method on the tumor is unknown. The sentence is incomplete. Amendment of the claims, for example, to recite "a hyperthermia method for treating a malignant tumor" will obviate the instant rejection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 4-6, 8, 9, 11, 12, 14, 15, 17, 18, 19, 20, 23, 24, 26, 27, 29, 30, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yanase et al (Jpn J Cancer Research, 1998, 89:463-470) in view of O'Day et al (Clinical Cancer Research, 2002, 8:2775-2781).

The claims are drawn to a hyperthermia agent for malignant tumor which comprises cytokine and magnetic fine particles, wherein the particles are magnetite covered by cationic liposome, wherein the agent contains cytokine and magnetic fine particles separately, wherein the cytokine is interleukin-2 (IL-2) or granulocyte macrophage-colony stimulating factor (GM-CSF), and a hyperthermia method of malignant tumor which comprises administering cytokine to malignant tumor, then the tumor is subjected to hyperthermia.

Yanase et al teach a hyperthermia agent for treating a malignant tumor comprising magnetite cationic liposomes (abstract) and a hyperthermia method for treating a malignant tumor (p. 464, col. 2 in Material and Methods; p. 469, col. 1 and 2). Yanase et al does not teach a method of using a cytokine with hyperthermia of a malignant tumor.

O'Day et al teach the administration of IL-2 and GM-CSF cytokines to treat cancer patients (abstract) and the improved survival in cancer patients with poor prognosis (p. 2780, cols. 1 and 2).

These references suggest the importance of each of these agents in anti-tumor treatment. However, the references are deficient in that they do not teach using these agents together. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the cytokines taught by O'Day et al and the hyperthermia agent and method taught by Yanase et al in combination in order to treat malignant tumors. One of ordinary skill in the art would have been motivated to use the cytokines, hyperthermia agent and method in combination in a method of treating a

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malignant tumor in view of the importance of eliminating tumor cells. Each of these agents had been taught by the prior art to be effective in the treatment of malignant tumors, thus the instant situation is amenable to the type of analysis set forth in In re Kerkhoven, 205 USPQ 1069 (CCPA 1980) wherein the court held that it is *prima facie* obvious to combine two modes of treatment, each of which is taught by the prior art to be useful for the same purpose in order to make a protocol that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. Applying the same logic to the instant process claims and composition claim, given the teaching of the prior art of processes using either a hyperthermia agent and method or a cytokine in the process of treating malignant tumors, it would have been obvious to treat malignant tumors with both a hyperthermia agent and method and cytokine because the idea of doing so would have logically followed from their having been individually taught in the prior art to be useful as agents for the same purpose of treating malignant tumors. One of ordinary skill in the art would have reasonably expected to obtain effective treatment of malignant tumors with any or both of cytokines, hyperthermia agent, and method since they had been demonstrated in the prior art to successfully treat malignant tumors.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura B Goddard, Ph.D.  
Examiner  
Art Unit 1642

SUSAN UNGAR, PH.D.  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "Susan Ungar", written in a cursive style.